FIRST

Do No Harm

In this Issue:

Patient Care Assessment Division, Board of Registration in Medicine

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PCA SEEKS TO BETTER DEFINE ITS MISSION

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"The Board of Registration in Medicine, in promulgating [the PCA regulations], has as its primary goal, ensuring that patients in both institutional and office settings receive optimal care." 243 CMR 3.01

During the past 6 months, the Patient Care Assessment Division (PCA) has been taking time to reflect on its role in the arena of patient safety and quality in the Commonwealth. What does PCA need to be? Not just a collector of reports, but a distributor of information. Not a narrow analyzer of unique reports, but a consensus builder of best practices for categories of errors, a claxon to avoid pitfalls. There are other organizations similarly involved in quality and patient safety initiatives that have worked hard to improve the quality of care for patients in the Commonwealth, such as the Department of Public Health, Joint Commission, Betsy Lehman Center, Massachusetts Coalition for Prevention of Medical Errors, Leapfrog, and the Institute for Healthcare Improvement. So why do we need PCA? For two very important and powerful reasons: (1) PCA can ensure physician involvement in patient safety and quality programs; and (2) reports made to PCA are provided statutory confidential protections. PCA is able to oversee, but not compromise, the peer review processes in health care facilities.

So how does PCA fulfill its mission? Our challenge is to achieve results using persuasive, collaborative, attractive strategies; to thread the needle between over- assertiveness which worsens relationships and too little which limits achievement. Some health care facilities argue that PCA has been neither efficient nor effective in improving patient safety, that the reports received from PCA only serve as a substrate for argument about who is right, the institution or the PCA reviewer. Many others acknowledge that PCA has been effective in identifying quality and patient safety systems that were functioning in name only, not truly the fabric of the institution. For those health care facilities, the authority of PCA was the impetus for the cultural change that was needed to make quality and patient safety the top priority at the governing board level.

Where does PCA begin? Keeping the "big picture" in mind is essential. All of us, as patients or potential patients, know that having a renowned physician doesn't assure that we will receive the best care. Successful healthcare must include everyone, from housekeeping to house officers. Our first step is the expansion of the PCA Committee. We now have a more diverse, multidisciplinary committee that includes health care quality experts and a patient advocate. We look forward to the new PCA Committee members being our "ambassadors" for change. As *Verizon* says, "it's the network."

Generating more reports is not the answer. It is about better reports. The Department of Public Health collects and investigates "Serious Reportable Events" (SREs) as defined by the National Quality Forum. Some SREs are also reported to PCA under the PCA regulations requiring the reporting of certain unexpected serious patient outcomes. SREs are only a small subset of the reports received by PCA. In fact, last year only 25% of the unexpected events reported to PCA met SRE reporting criteria. It is through the review of those "non-SRE" reports that we have been able to understand how institutions identify quality problems, determine causes of the problems and implement solutions. Our goal for 2009 is to find the best way to use the information we receive in reports to PCA to make patients safer in the Commonwealth. We look forward to working with the newly expanded PCA Committee, the other organizations involved in patient safety and quality, and most importantly with the individual health care facilities to meet this challenge.

By improving the efficiency and expediency in its methods for overseeing patient care in hospitals, PCA will be able to focus more on how it can assure quality patient care in the office setting. As with the institutions, it is only with collaboration and consensus building that this work can be done. These efforts are ongoing. PCA is working closely with the Massachusetts Medical Society and physicians leaders in the state on strategies for improving credentialing practices, statewide. We look forward to making great strides in this initiative in 2009.

"VISION WITHOUT IMPLEMENTATION IS INEFFECTIVE."

Joseph S. Nye in THE POWERS TO LEAD

SOUTHCOAST HOSPITALS GROUP REDUCES INSULIN ASSOCIATED ERRORS

The following Southcoast Hospitals Group actions to reduce errors with insulin products have resulted in a 45% reduction in insulin-associated medication errors. These initiatives were developed through the combined efforts of Southcoast's medical staff, and nursing and pharmacy services:

1. Prior to administering a dose of insulin, a second nurse is required by policy to perform a second check, verifying the dose and the type of insulin against the medication administration record.

2. Insulin is designated as a high alert medication requiring special procedures such as the second nurse verification, as well as unique storage and dispensing.

a. U-500 insulin is only stored within the pharmacy. All doses of U-500 insulin are individually prepared, labeled and dispensed by the pharmacy.

b. Insulin vials approved for storage in patient care areas are color coded. Each type of insulin is assigned a color and is stored within a color code bin and labeled with the same color label. This ensures that the insulins are stored separately to avoid confusion and possible error in selecting the wrong product.

3. A physician's preprinted sliding scale insulin order sheet was created to eliminate illegible orders and eliminate the practice of abbreviating units with "u".

a. The order sheet provides four different intensity levels of sliding scales to address different patient populations and conditions. It has been readily adopted by the medical staff and has eliminated errors with poorly written orders, confusion between the various insulin types, as well as the incorrect interpretation of the abbreviation of units for an additional zero. The order sheet also lists a four step algorithm for the treatment of hypoglycemia.

4. In conjunction with the sliding scale order sheet, a corresponding page on the Nursing medication administration record (MAR) for the documentation of all administered sliding scale insulin doses was developed and implemented.

a. This computer generated document is produced after review by a Pharmacist. The insulin MAR page is specific to the scale ordered eliminating handwritten transcription of the orders. The sliding scale is presented as a two column table including the glucose level and the amount of insulin to be administered. This eliminates the potential of incorrectly transcribing the order and legibility concerns on the MAR.

b. The MAR sheet prompts the nurse for appropriate documentation by providing a specific location for the patient's glucose level value, the initials of the nurse administering the dose, as well as that of the nurse performing the required second check.

c. The MAR sliding scale page contains immediate steps to be taken by the nurse for hypoglycemia and hyperglycemia.

5. For non-sliding scale insulin doses a computer generated MAR page is printed from the Pharmacy. This page documents administered insulin doses with specific locations and prompts for glucose levels and nurse initials. This page also contains a table of the various insulin products classified by the onset of action, as well as the brand and generic names. This helps to avoid confusion and reduce the potential of administering the wrong insulin type.

6. Insulin products with the potential for name confusion or mix-up were added to the Hospital's Look-alike/Sound-alike (LASA) list.

a. Designation as a LASA medication prompts the pharmacist to verify the appropriateness of the order during order review and computer entry. The Pharmacist must respond to this computer prompt that such actions have been taken before completing the order.

b. The LASA designation also generates specific warnings on the labels placed on the insulin vials, as well as similar warnings on the MAR, alerting the nurse to avoid potential confusion with this insulin type.

7. For the long acting insulin products, the pharmacist includes a specific administration time onto the MAR to reduce errors associated with missed doses.

8. SHG has worked to increase Nursing and Medical Staff education and awareness regarding the errors with insulin.

a. Data regarding the prevalence of insulin errors and the source of the errors is routinely reviewed and discussed at various forums and committees

b. A colorful poster entitled "Pause to avoid a medication error" lists insulin as the medication most frequently associated with errors. The poster has endearing animal paw prints across it, playing off the association of Paws and Pause for medication awareness. The posters are located throughout the hospital in all areas where medications are stored as well as at physician lounges and entrances.

Thank you to Robert Motha, RPh, Director of Pharmacy, Southcoast Hospitals Group, for contributing this article.

PCA REVIEWS PERINATAL SQRS

The Patient Care Assessment (PCA) Division reviewed 46 Safety and Quality Reviews reporting unexpected perinatal disability or death.[1] The following types of unexpected outcomes were identified: fetal demise (16)[2]; hypoxic ischemic encephalopathy (HIE) (5); fracture during delivery, including skull, shoulder, clavicle, humerus, and femur (11); embolic stroke (3); cerebral bleed (3); circumcision without consent (1); sepsis (1); hyperbilirubinemia (1); medication error causing respiratory compromise (2); bilateral pneumothoraces (1); respiratory depression at birth requiring resuscitation without evidence of sequelae (1); and unexpected death post delivery without identified cause (1). One of the above-noted cases of HIE and one case of clavicular fracture were reported as being a complication of shoulder dystocia.

Maternal complications were reported in 14 of the cases and included: group B strep colonization (4); gestational diabetes (3); placental abruption (2); pre-eclampsia (2); cardiac arrest after high spinal (1); methadone-associated complications (1); and; bladder tear during cesarean section associated with adhesions (1).

Contributing factors to the outcomes included the following:

Assessment/Clinical Judgment: delay in recognizing signs and symptoms of fetal distress; incorrect interpretation of fetal heart tracings; mother's heart rate confused with neonate's; delay in exam by OB; and prolonged second stage of labor.

Protocol/Guidelines: failure to follow protocol for continuous fetal heart monitoring prior to delivery; inability of hospital to meet ACOG guidelines for "decision to incision;" OB not compliant with ACOG guidelines regarding minimum gravida date for scheduled cesarean section; and non adherence to protocol for medication administration.

Communication: delay in notification of OB regarding patient's admission; language barriers between patient and caregivers; OB not responsive to nursing staff concerns; Certified Nurse Midwifes (CNM) failure to follow protocol for notification of OB of non-reassuring fetal heart tracing.

Administrative: delay to cesarean section due to OR scheduling issues.

While some hospitals reported that no quality concerns were identified, many of the reporting hospitals implemented actions to prevent occurrences and improve patient care. The following are examples of the actions taken.

- Development of a hospital based program for Nurses and CNMs to demonstrate annual competency in interpretation of fetal heart tracing.
- Requirement for review/interpretation of fetal heart tracings at hand-off of care.
- Implementation of OB team training in the performance of neonatal resuscitation.
- Monitoring of compliance with hospital policies and ACOG Guidelines through direct observation and chart review.
- Development of a protocol for enhanced OB/CNM communication and monitoring CNM practice.
- Improved management of Pitocin: addition of requirement for documentation of Bishop score to Pitocin orders; annual competencies on Pitocin management.
- Implementation of staff drills and team training to better manage shoulder dystocia.

Careful review of these events provided opportunity for all of the hospitals involved to review and improve their obstetrical protocols, education and training requirements, and methods of communication between the various caregivers, RN, CNM and OB. Improved quality care for future patients was the focus of the reviews, regardless of whether or not the hospitals determined that the reported events were preventable.

Because PCA does not have specific requirements for the content of the SQRs, many of the reports lacked the detail that would have made this PCA analysis more comprehensive and informative. In the future, when reporting cases of perinatal disability or death, please include the following in your report: maternal age; relevant maternal history; gestational age; Apgars; maternal complications; method of delivery; induction or augmentation; tocolytic (type, duration and reason); time of admission to time of 2d stage labor; duration of 2d stage labor; time of delivery; use of internal monitor; evidence of fetal distress (e.g. meconium); and summary of findings from review of fetal heart tracings.

[1]This is a review of Safety and Quality Review (SQR) reports received during the time period January 2005 through November 1, 2008. The cases were reported under PCA regulations 243 CMR 3.08 (2) (d): deaths or major impairments of bodily function that are not ordinarily expected as a result of the patient's condition on presentation.

[2]For purposes of this review, the cases categorized under fetal demise involved those infants that did not breathe or show any other signs of life at the time of delivery. The gestational ages in the reported cases were 24-31 wks (4); 32-37 wks (5); 38-41 wks (5); and unknown (2).

NURSING EXCELLENCE DRIVES REIMBURSEMENTS

Lisa O'Connor, RN, BSN, MS, CNAA, Vice President of Nursing, Boston Medical Center

Nursing has a legacy of commitment to caring and now the Centers for Medicare and Medicaid has enacted its pay for performance strategy. How did we get to this place? Here we are for the first time in American health care history finding the federal government willing to withhold dollars for unfavorable patient outcomes. Barely a decade ago, the Institute of Medicine revealed (exposed) to the world the sobering issues in our hospitals. Hence, we now find ourselves with the only thing that may solidify healthcare quality as an imperative…to be money. Critics of the CMS methodology feel that the burdens for these new incentives bear heavily on nurses. I would argue that the "burden" of keeping patients safe has always been the primary responsibility of the nurse at the bedside. The only nuance about this is that our results are being made public. Accordingly now, if our outcomes are less than ideal we will not be paid. Hospital acquired decubitus ulcers, foley catheter related urinary tract infections, and falls…to name a few….all of these are the responsibility of the nurse.

In 1859, Florence Nightingale's Notes on Nursing revealed this very notion. "If a patient is cold, if a patient is feverish, if a patient is faint, if he is sick after taking food, if he has a bed-sore, it is generally the fault not of the disease, but of the nursing."

CMS has given nursing the opportunity to deliver what it does best…excellence in patient outcomes.

"FOUND UNRESPONSIVE:" WHEN, WHERE, WHY?

"The patient was found unresponsive…." The frequency with which PCA Quality Analysts see this phrase in the Safety and Quality Reviews (SQRs) submitted by hospitals has triggered a "look back" at the reports to see what we can learn from these cases. PCA analysts searched through over 4500 SQRs with incident dates between 2000 and 2008, and identified 215 SQRs that describe the patient as being found unresponsive at the time of the reported unexpected event.

Preliminary review has revealed the following findings. 54% of the events occurred between 12:00 midnight and 8:00 am; 19% between 8:00 am and 4:00 pm; and 27% between 4:00 pm and 12:00 midnight. While the majority of these events (76%) occurred on adult medical surgical units, 9% of the events occurred on psychiatric units; 11% occurred on rehabilitation units; and 4% occurred on pediatric units. Further breakdown showed that 2% of the events occurred in the Intensive Care Unit, 3% in the Emergency Department and 10% in Telemetry.

In 43% of the cases, the Quality Analysts noted that there were concerns as to whether the nursing and medical staff recognized and appropriately monitored hemodynamic changes in the patients. Failure to follow monitoring policies was a finding made in 17% of the cases. In 17% of the reports, the patients had received anxiolytics or narcotics shortly before the events.

PCA Quality Analysts will be looking at these reports in more detail to identify any specific trends or valuable "lessons learned." We recommend that health care facilities reinforce monitoring policies and guidelines, and assure that medical and nursing staff are able to assess hemodynamic changes in their patients and recognize when intervention is needed.

Most hospitals require annual electronic fetal heart monitoring competencies for nursing staff. Why not require annual competencies for Obstetricians and Nurse Midwives?

A Leader in Health Care Reform: Florence Nightingale's work in instituting clean and sterile techniques, in recognizing the need for proper nutrition and in reorganizing patient care was successful in decreasing the death rates in hospitals during the Crimean War. Her reforms in hospital administration and patient care were soon adopted throughout the world and she became an international authority on health care, even advising the United States Military on how to care for wounded soldiers during the Civil War.

PCA WELCOMES NEW MEMBERS TO THE PCA COMMITTEE

The PCA Committee recently expanded to include seven new members. They all bring valuable experience in clinical practice, quality and patient safety. A brief introduction follows.

Evan Benjamin, MD is Associate Professor of Medicine at Tufts University School of Medicine and Chief Quality Officer for Baystate Health in Springfield, Massachusetts. Dr. Benjamin directs the Division of Healthcare Quality at Baystate Medical Center where he oversees the operations and research goals of the division. Dr. Benjamin speaks nationally regarding the impact of our healthcare delivery system on the quality of healthcare; serves on a number of advisory panels, journal editorial boards and national committees; and is published in both peer reviewed and non-peer reviewed publications. Dr. Benjamin is on the board of Catholic Healthcare Partners, a 35 hospital non profit system based in Ohio where he chairs the board quality committee. His recent work appearing in the New England Journal of Medicine has helped to frame policy questions for improving our healthcare system.

Susan Haas, MD currently serves as Specialty Director, Obstetrics and Gynecology, at Harvard Vanguard Medical Associates, where she also chairs the Quality Assurance Committee. Previously she held the positions of Vice Chair, Obstetrics and Gynecology, and Chief Medical Officer at Boston Medical Center. While at BMC she chaired the Medical Executive Committee and established and chaired the Clinical Quality Council. Dr Haas is a graduate of Harvard Medical School and the Harvard School of Public Health. She practices Ob/Gyn in her Boston office and at Brigham and Women's Hospital.

Patricia Hughes, BSN, MSN, CPHRM received her BSN from Fitchburg State College and her MSN from the University of Lowell. Ms. Hughes was also certified as a Family Nurse Practitioner and has her CPHRM. She is currently Director of Clinical Risk Management at UMassMemorial Medical Center in Worcester, MA. Ms. Hughes plays an active role in the self insurance captive at UMassMemorial and oversees the management of clinical risk operations at the Medical Center. In addition to adverse event management, there is a strong focus on proactive risk assessment, loss prevention strategies and education, liability identification and claims management and QI/patient safety initiatives.

Robert J. Schreiber, MD has been Physician-in-Chief at Hebrew Senior Life (HSL) for the past four years. Board certified in internal medicine and geriatric medicine, Dr. Schreiber was the first Chairman of the Department of Geriatrics at Lahey Clinic in Burlington, MA. He developed innovational programs for care management that focused on geriatric care management of community dwelling elders. Dr. Schreiber is a Clinical Instructor of Medicine at Harvard Medical School and lead the development of a program for community dwelling older adults called Healthy Eating for Successful Living ™, an evidence-based nutritional program that stresses heart and bone health at some of the HSL housing sites and in other parts of the Commonwealth. Dr. Schreiber has been working closely with the Commonwealth's Executive Office of Elder Affairs and the Department of Public Health to bring self-management strategies to older adults in the community .

Leslie Sebba, MD received his Medical Degree at the University of Cape Town in South Africa. He is a Board Certified Internist and Pulmonologist. Dr. Sebba practiced Pulmonary Medicine for 18 years on the North Shore in Peabody and Lynn. He has been the Medical Director of Northeast PHO at Beverly Hospital, and was Medical Director at Tufts Health Plan. Dr. Sebba is currently serving as Chief Medical Officer at Anna Jaques Hospital in Newburyport, where he has been for the past 4 years.

Marc Rubin, MD has been Chair of the Department of Surgery at North Shore Medical Center since 2005 and is a Clinical Instructor in Surgery at Harvard Medical School. Board certified in both General and Colon and Rectal Surgery, Dr Rubin has a busy clinical practice and is President of Surgical Specialists of the North Shore, a large multispecialty surgical group. At NSMC Dr Rubin has developed and implemented a number of innovative safety and quality programs and is a member of both the Patient Care Assessment Committee and the Quality and Professional Affairs Committee. He has served as Associate Editor of the journal Diseases of the Colon and Rectum and sits on the Quality and Safety Committee of the American Society of Colon and Rectal Surgeons. He is a member of the Board of Directors of the North Shore Health System and was recently named President-elect of the Massachusetts Chapter of the American College of Surgeons.

Nicola B. Truppin, JD is the founder and principal of Health Navigator Partners, LLC, based in Newton, Massachusetts, a company dedicated to helping patients navigate the complex health care system. Ms. Truppin has a JD from Suffolk Law School, was trained in Health Care Negotiation and Conflict Resolution at the Harvard School of Public Health and was the administrator for Harvard Medical School clinical courses at both MGH and BIDMC. She served as Manager of Member/Provider Appeals & Grievances at Tufts Health Plan and her current work involves collaborative health care problem solving with patients, providers and employers. She is co-author of the chapter, "Using the Law to Strengthen the Patient's Voice" in Patient Advocacy for Health Care Quality: Strategies for Achieving Patient-Centered Care. Eds. Earp, French, Gilkey. Sudbury: Jones & Bartlett, 2008. In addition Ms. Truppin also coordinates the health care practice of The Mediation Group in Brookline, Massachusetts. She is a member of the Consumer Health Quality Council of Health Care for All and is a leader of the health care section of the Association for Conflict Resolution.

PCA: WHAT HAVE WE SEEN?

During the first three quarters of CY 2008, staff reviewed over 627 SQRs. While the reports can be categorized in a number of ways, based on the description of the event and the health care facility's review findings, here is a general breakdown of the types of cases that were reviewed. Of the cases reviewed for CY Q2 and Q3, 166/429 (39%) were reported as patient deaths.

SQRs Reviewed by PCA January 1- September 30, 2008	Q1	Q2	Q3
Perioperative or Post-procedure MI or Stroke	8	11	13
Wrong site or procedure	11	11	8
Retained foreign body	7	6	9
Surgical laceration or perforation	16	18	16
Wound dehiscence/anastomotic leak or disruption	7	2	2
Post surgical medical management	2	4	5
Post-surgical Infection	10	6	8
Surgical complications (other)	6	12	4
Embolism (pulmonary or air)	6	3	10
Anticoagulation management	11	0	4
Sepsis management	4	1	6
Perioperative Arrest	NC*	6	0
Anesthesia complications (other)	4	4	3
Endoscopy complications	11	10	6
Catheter placement issues (IJ, Epidural, NJ, IV)	13	1	7
Radiological procedure related complications (including Interventional Radiology)	5	5	7
Medical Management	11	18	12
Post-Partum Hemorrhage w/hysterectomy	NC*	2	3
Obstetrical management (other)	6	9	10
Medication error	8	14	11
Equipment failures/problems	3	2	0
Chemotherapy related	4	0	1
Transfusion related	NC*	0	1
Missed or delayed diagnosis	10	22	9
Falls with serious injuries or death	17	47	30
Psych Related (suicide /suicide attempt/psych elopement)	NC*	5	4
Rehab/LTAC (transfer related or falls)	14	4	1
Found Unresponsive	NC*	6	6
Other	4	1	3
Total	198	230	199

* NC -Not Counted for this Quarter

PCA NOTES

Hallmark Health System's Fall Team meets regularly to monitor the fall rate for Lawrence Memorial and Melrose Wakefield Hospitals. Both hospitals have had a downward trend in their fall rates. Hallmark attributes this improvement to the nursing staff implementation of "patient care huddles" to discuss patients who are at risk for fall; and hourly rounding on high risk patients. Hallmark also recently purchased bed/chair alarms which allow a patient's family member to pre-record a message to the patient. The message will play when the patient tries to get out of the bed or chair, reminding him or her to sit down and wait for assistance. The alarm also has an audible ring that notifies staff that the patient needs attention.

Retained Foreign Body: PCA received an SQR involving a retained foreign body post hemi-laminectomy and diskectomy. Micropatties were used intraoperatively to tamponade bleeding sites. At the end of the procedure the surgeon used the strings attached to the micropatties to remove them, but one of the strings no longer had a micropatty attached. Despite attempts to locate the micropatty, which included plain films and fluoroscopy, the object could not be located and the wound was closed. The micropatty was subsequently located on CT, the pt was returned to the OR and the object was successfully removed. On Root Cause Analysis the packaging for the micropatties was examined and revealed a warning that the strings were not to be used for removal. This recommendation had not been noted by the surgical team.

The SQR form has been revised. The new form and instructions are at the following links:

SQR Form PDF Version

http://www.massmedboard.org/pca/pdf/sqr_form_oct_2008.pdf

SQR Form Word Version

http://www.massmedboard.org/pca/pdf/interactiveform_aug_2008.doc

SQR Form Instructions

http://www.massmedboard.org/pca/pdf/mir_instructions.pdf

SQR Form Basis Codes

http://www.massmedboard.org/pca/pdf/mir_basis_codes.pdf

Reminder. PCA regulations require that healthcare providers who are employed or have privileges at a health care facility must be provided written notice, at least annually, of the requirements and rights in MGL c. 112 sec. 5F. This law states that a physician or other health care provider must file a report (a "5F report") with the Board of Registration in Medicine when he or she has a reasonable basis to believe that a physician is in violation of Massachusetts General Laws Chapter 112, §5, or any of the Board's regulations. Such violations include substandard care, prescription violations, insurance fraud, sexual misconduct or other boundary violations, and practicing while impaired (although there are exceptions in some impairment cases). If the report is filed in good faith, state law protects the reporter from being discriminated against by an employer for reporting. Information for health care providers on how to report under this law is available at the Board's website: http://www.massmedboard.org/data_repository/peer_reports.shtm. Any questions about reporting under this law should be directed to the Board's Data Repository Counsel at (781) 876-8200.

CONTACT PCA

To be added to the PCA Newsletter and advisory mailing list, update hospital contact information, submit an article, request an SQR form, or obtain additional information, contact PCA: maureen.keenan@state.ma.us or (781) 876-8255. Send mail to MA Board of Registration in Medicine, PCA Division, 200 Harvard Mill Square, Suite 330, Wakefield, MA 01880.

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